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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,755	08/23/2000	Gijs van Rooijen	9369-153/MG	1008

1059 7590 03/25/2003

BERESKIN AND PARR
SCOTIA PLAZA
40 KING STREET WEST-SUITE 4000 BOX 401
TORONTO, ON M5H 3Y2
CANADA

EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/25/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/643,755

Applicant(s)

VAN ROOIJEN ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 6 January 2003, paper number 14, including the 37 C.F.R.1.132 declaration of Gijs van Rooijen.

Applicant has cancelled claims 2 and 4, and amended claims 1, 3, 8, 11, 17, 18 and 19.

Claims 1, 3, 5-28 are pending, claims 24-28 are withdrawn as drawn to non-elected invention(s).

2. This action is made FINAL necessitated by Applicant's amendment.

3. All rejections not addressed below have been withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. A copy of Applicant's IDS, paper no. 15, dated 6 January 2003, is included with this office action.

6. The 37 C.F.R.1.132 declaration of Gijs van Rooijen, dated 18 December 2002, is acknowledged. This declaration includes experimental information and details of chymosin production in plant seed other than Brassica napus, namely safflower, flax, and Arabidopsis, using the claimed method.

Specification

7. The Specification is objected to as containing new matter: "incorporation herein by reference in its entirety". While Applicant may claim priority to a parent application,

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incorporation by reference may constitute new matter because it would also include the prosecution history and all papers submitted in said parent application. It is suggested that Applicant delete the "which is incorporated herein by reference in its entirety" recitation.

Claim Rejections - 35 USC § 102

Claims 1, 3, 5-7, 11, and 13-19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Willmitzer et al (WO 92/01042) (specification, p 3). Willmitzer teaches a method for the production of chymosin in a plant seed comprising introducing into tobacco and potato plant cells a chimeric nucleic acid sequence comprising a seed-specific phaseolin promoter, a nucleic acid sequence encoding pro-peptide chymosin, and a terminator, then growing the plant until it sets seeds and obtaining chymosin-containing seeds (Abstract, p 4, 5, 10 and 13). Seeds obtained from the transgenic plants are tested to assure that the gene of interest is present. The expressed enzyme can be isolated from the seed (p 3). Willmitzer further teaches including a plant signal sequence (p 5). The pro-chymosin of Willmitzer appears to a mammalian chymosin obtainable from a bovine, sheep, or goat source (p13), since these are the only known nature sources of chymosin (specification, p.1). Since the method of Willmitzer is the same as Applicant's method, and teach the same promoter as preferred by Applicant, the percentage yields would have been an inherent property of the DNA construct used.

Applicant traverses, stating primarily that Willmitzer does not disclose the production of a transgenic plant wherein at least 0.5% of the total seed protein is chymosin, and that Willmitzer only achieves the production of 0.1% - 0.5% chymosin of the total soluble protein.

Applicant's traversal has been considered and is unpersuasive because since the method of Willmitzer is the same as Applicant's and teaches the same promoter as preferred by Applicant, the percentage yields would have been an inherent property of the DNA construct used. If Applicant's percentage yields are different from that of Willmitzer, it is suggested that Applicant amend the claims to include specific element(s) and structures which would result in the production of a seed containing at least 0.5% (w/w) chymosin.

Accordingly Willmitzer anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. Claims 1, 3, 5-8, 10, 11, and 13-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Willmitzer (WO 92/01042) as applied to claims 1, 3, 5-7, 11, and 13-19 above, and further in view of Applicants admitted prior art. The teachings of Willmitzer are discussed supra.

Applicant traverses, stating primarily that Willmitzer discloses a number of plant parts other than seeds, and that Willmitzer's Example 1 involves the use of a 35S CaMV promoter to drive expression of chymosin, and that this promoter yields only 0.1%-0.5% chymosin as total soluble protein from the plant. Applicant further states that the 35S

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CaMV promoter is an art recognized strong constitutive promoter. Applicant further asserts that Willmitzer does not suggest the use of a seed-specific promoter as a means of enhancing expression of chymosin in seed.

Applicant's traversal has been considered and is unpersuasive because Willmitzer teaches the phaseolin promoter, the same seed-specific promoter as exemplified by Applicant.

While Willmitzer teaches the inclusion of a plant signal sequence and terminator in a chimeric construct, Willmitzer does not specifically teach a tobacco PR-S signal sequence and phaseolin terminator. However, the inclusion of a heterologous signal sequence and terminator in a chimeric construct was notoriously well known in the art, as evidenced by the numerous examples set forth by Willmitzer (p. 5) as well as by Applicant (p. 9 and 12).

Applicant's admitted prior art indicates that a tobacco PR-S signal sequence and phaseolin terminator, as well as their biological properties, were also known at the time the invention was made (p. 9 and 12). Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize any of the known plant signal sequences and terminators of the prior art, including the claimed tobacco PR-S signal sequence and phaseolin terminator, for their known biological properties, in the chimeric construct for expressing the chymosin of Willmitzer without any surprising or unexpected results. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

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9. Claims 1, 3, 5-8, and 10-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Willmitzer (WO 92/01042) as applied to claims 1, 3, 5-8, 10, 11, and 13-23 above, and further in view of Adang et al (US 5,380,831). While Willmitzer does not teach optimizing the codon usage of the nucleic acid sequence encoding chymosin for use in plants, such practice was well known in the prior art, as evidenced by Adang. Adang teaches expressing a heterologous protein (Bacillus thuringiensis toxin gene) in plants utilizing codons preferred in highly expressed plant proteins. Accordingly, one skilled in the art would have been motivated at the time the invention was made to express a heterologous protein such as chymosin using plant preferred codons for the purpose of optimizing expression of the protein of interest with a reasonable expectation of success.

Applicant traverses, stating primarily that Willmitzer has deficiencies and that Adang does not remedy them.

Applicant's traversal has been considered and is unpersuasive because of reasons discussed supra, and because the deficiency of Willmitzer of not teaching optimized plant codon usage is in fact remedied by Adang and proper motivation is given.

Remarks

10. SEQ ID NO: 1 is free of the prior art.
11. No claim is allowed.
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

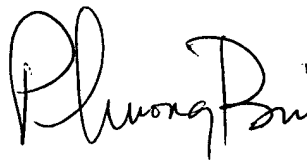
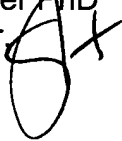
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner
March 20, 2003



PHUONG T. BUI
PRIMARY EXAMINER